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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,915	11/18/2003	John Cooker	COO 20200	5654

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,915	COOKER, JOHN	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION..

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,8,12,18,20-24 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,8,12,18,20-24 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, Amended Claims and 132 Declaration filed on 07/09/07 is acknowledged.

Claims 1-4, 7, 9-11, 13-17, 19 and 25-36 have been cancelled by the Applicants in this Application.

Claims 5, 6, 8, 12, 18, 20-24 have been amended by the Applicants and new claim 37 have been added in the Application.

Accordingly, claims pending in the prosecution are 5, 6, 8, 12, 18, 20-24 and 37.

2. The Double Patenting rejections over (U.S. Patent 6,656,501) and copending Application No. 10/956301 is hereby withdrawn in view of terminal disclaimer filed by Applicants.

The following rejections are necessitated by Applicant's Amendments.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims **5, 6, 8, 18, 20-24 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (U.S Patent No.5, 198, 229) in view of Sherwood et al. (U.S Patent No. 5,725,884) and further in view of Newton et al. (4,938,967).

Wong et al. teaches a capsule comprising an active agent (col. 8, lines 54 and col. 9, line 22) and excipients (col. 8, lines, 6-17). The capsule comprises a buoyancy chamber with a low density to allow the device to float within or on the surface of fluid (col. 10, 28-41). The capsule also comprises a high- density portion so that the device sinks (col. 10, lines, 42-54). The low density is in the range of from about 0.5 to about 0.7 (column 10, lines, 32-35). Wong et al. further discloses that the active agent formulation comprises the active agent to be delivered, as a liquid, solid, semisolid. It may additionally include dosage forms comprising the active agent which are capable of maintaining their physical configuration and chemical integrity while housed within the dispenser. These include, without limitation, tablets with or without a density element; matrix tablets; spheres; pellets and elongated tablets; capsules (column 7, lines, 55-65). The method of making density augmented capsule is depicted in column 11, lines 55-65). Wong et al. do not disclose excipients such as fillers as microcrystalline cellulose, lactose as claimed in the instant application. Sherwood et al. disclose fillers such as microcrystalline cellulose, lactose sorbitol as claimed.

Sherwood et al. discloses a microcrystalline cellulose-based excipient having improved

Compressibility. The excipient is an agglomerate of microcrystalline cellulose particles and from about 0.1% to about 20% silicon dioxide particles, by weight of the microcrystalline cellulose, wherein the microcrystalline cellulose and silicon dioxide are in intimate association with each other (abstract). Another commonly used class of excipients in solid dosage forms are binders. Binders are agents which impart cohesive qualities to the powdered material(s). Commonly used binders include starch, and sugars such as sucrose, glucose, dextrose, and lactose (column 1 , page 55-60). A processed cellulose, microcrystalline cellulose, has been utilized extensively in the pharmaceutical industry as a direct compression vehicle for solid dosage forms. Micro-crystalline cellulose is commercially available under the tradename EMCOCEL.RTM..RTM. from Edward Mendell Co., Inc. and as Avicel.RTM. from FMC Corp. Compared to other directly compressible excipients, microcrystalline cellulose is generally considered to exhibit superior compressibility and disintegration properties. (column 2, lines 42-50). The present invention is further directed to a method of maintaining and/or enhancing the compressibility of microcrystalline cellulose. The method includes forming an aqueous slurry containing a mixture of microcrystalline cellulose and silicon dioxide having a particle size from about 1 nm to about 100 .mu.m, and drying the slurry to obtain microcrystalline cellulose-based excipient particles in which the silicon dioxide particles have been integrated with the microcrystalline cellulose particles. Within this aspect of the invention, the slurry contains from about 0.5% to about 25% by weight microcrystalline cellulose, with amounts of from about 15% to about 20% being preferred (column 6 lines, 10-12).

Typically, microcrystalline cellulose has an apparent density of about 0.28 g/cm.sup.3 and a tap density of about 0.43 g/cm.sup.3. Handbook of Pharmaceutical Excipients, pages 53-55 (column 7, lines 45-47). In addition to one or more active ingredients, additional pharmaceutically acceptable excipients (in the case of pharmaceuticals) or other additives known to those skilled in the art (for non-pharmaceutical applications) can be added to the novel excipient prior to preparation of the final product. For example, if desired, any generally accepted soluble or insoluble inert pharmaceutical filler (diluent) material can be included in the final product (e.g., a solid dosage form). Preferably, the inert pharmaceutical filler comprises a mono-saccharide, a disaccharide, a polyhydric alcohol, inorganic phosphates, sulfates or carbonates, and/or mixtures thereof. Examples of suitable inert pharmaceutical fillers include sucrose, dextrose, lactose, xylitol, fructose, sorbitol, calcium phosphate, calcium sulfate, calcium carbonate, "off-the-shelf" microcrystalline cellulose, mixtures thereof, and the like (column 12, lines, 23-35). The tablet can be coated (column, 12, lines 63-65). the novel excipient can be utilized in other applications wherein it is not compressed. For example, the granulate can be admixed with an active ingredient and the mixture then filled into capsules. The granulate can further be molded into shapes other than those typically associated with tablets. For example, the granulate together with active ingredient can be molded to "fit" into a particular area in an environment of use (column 15, lines 20-30). In example 7-12, the amount of microcrystalline cellulose is much more than active ingredient.

Newton et al. teaches that the residence time in the human stomach of pharmaceutical, gastric controlled release, solid units can be increased significantly if the units have a density that is much higher than normal. A preferred oral dosage form according to the invention comprises a capsule or other dosage form (abstract). Newton et al. further disclose that the selection of the binder (including its manner of application) determines the rate of release of the active ingredient from within each unit. For instance if the binder is readily soluble in gastric juices the unit will disintegrate rapidly upon entry to the stomach, giving substantially immediate release of all its active ingredient. If the binder (which may be a matrix binder or, more usually, a coating around the unit) is a gastric controlled release binder it will not permit disintegration upon entry to the stomach but will instead permit permeation, at a preselected time and rate, of active ingredient into the gastric juices. This makes the active ingredient available within the stomach and also within the upper intestine into which the stomach fluids are expelled (column 1, lines, 20-35). Examples 1-3 depict microcrystalline cellulose as binders and Newton et al. further state that binders are well known and generally comprise hydrophobic acrylic polymers or cellulose derivatives, vinyl polymers and other high molecular weight natural polymer derivatives or synthetic polymers (see column 9, lines 20-25). Newton et al. also suggest adding fillers to the formulations to improve the properties of the binder. Thus, Newton et al.'s invention proves that density plays an important role in aiding the residence time of the formulation.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to add filler/binder such as microcrystalline cellulose or lactose or

other fillers as claimed instantly in the formulation of Wong et al. in view of Sherwood et al. and Newton et al. because Newton et al. teaches that predetermined weight of binder/filler in a dosage form such as capsule helps in increasing density of the formulation which in turn helps in increasing residence time of the capsule or helps in letting the capsule sink in the gastrointestinal tract and Sherwood et al. teaches the advantages of various fillers such as microcrystalline cellulose and lactose etc. in the dosage forms. A skilled artisan would thus have formulated a capsule comprising microcrystalline cellulose as a filler having predetermined weight that increases the density of the capsule to let the capsule sink with a reasonable expectation of success.

5. Claims **5, 6, 8, 18, 20-24 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff (U.S Patent No. 5,098,425) in view of Sherwood et al. (U.S Patent No. 5,725,884) and further in view of Newton et al. (4,938,967).

The teachings of Sherwood et al. and Newton et al. have been discussed above. Eckenhoff teaches a dispensing device wherein a capsule contains a composition comprising a beneficial agent and a composition comprising a hydrogel and a denser member (column, 17, claim 1). The dense member increases the density of hydrogel composition to impart an initial density of greater than 1 to 8 (column, 10, lines 3-39). The hydrogel composition with the dense member is located at one end of the device as seen taught in the drawings of the reference. The thermo-responsive formulation and the delivery means perform in concert for dispensing a beneficial agent through

passageway means to an animal over a prolonged period of time (abstract). Eckenhoff does not expressly teach the fillers as claimed such as microcrystalline cellulose or lactose and weighting device effects of the swallowing of the device. However based on the teachings of Sherwood et al. and Newton et al., as discussed in the rejection above, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make a dosage form with a filler that is denser than the device substance contained in the dosage form that the filler is located in one end of the dosage form. It is obvious that if a dosage form is heavier at one end, that end will point towards the pharynx in view of Newton et al.. One of ordinary skill in the art would have been motivated to do this to achieve sinking of the dosage form or retention of the device in the stomach. Hence, the invention was prima facie obvious as a whole to one of ordinary skilled in the art at the time the invention was made.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff (U.S Patent No. 5,098,425) in view of Sherwood et al. (U.S Patent No. 5,725,884) and further in view of Newton et al. (4,938,967) and Voss et al. (US patent No. 4,548,825).

The teachings of Eckenhoff et al., Wong et al. and Sherwood et al. have been discussed above. Eckenhoff et al., Wong et al. and Sherwood et al. do not disclose indicia on the tablet or capsule. Voss et al.'s disclosure relates to the non-contact printing on pharmaceutical tablets, tablet cores, and tablet-like food (abstract).

Voss et al. discloses that the safety of application of such pharmaceutical forms with indicia is increased if, for example, with regard to different doses of the same active substance, clearly visible special codings are printed on moldings to minimize confusion or if the pharmaceutical form is lettered with the specification of the quantity of active substance (column, 6, lines 40-45).

It would have been obvious to one of ordinary skilled in the art at the time the invention was made to prepare capsules with indicia because it increases the safety and also makes it visibly clear to the patient to take the correct medicine. An indicia also increases the aesthetics which would have been within the purview of a skilled artisan at the time the invention was made. A skilled artisan would thus have been motivated to prepare tablet with indicia to make it easier, safer and convenient for the patients with a reasonable expectation of success.

Response to Arguments

7. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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